

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 1:22-cv-00061-TSK

**DEFENDANT MYLAN PHARMACEUTICALS INC.’S
POST-HEARING SUPPLEMENT**

During the Status Conference, the Court asked Plaintiff’s counsel what would become of the patents remaining if only six of the 24 patents currently asserted are ultimately the subject of a first trial. Regeneron had no concrete answer, and instead only vaguely suggested it would not pursue preliminary injunctive relief on those remaining patents. The response did not address the enormous burden on the Court and Mylan of a second wave of litigation, the timing and scope of which is now unknown, and the unfairness of giving Regeneron “multiple at-bats,” but also failed to address another relevant provision of the BPCIA.

Under the BPCIA, at the conclusion of the “patent dance” Regeneron had 30 days within which to select patents from the negotiated list on which to sue, if it wished to preserve a right to seek lost profits damages. For litigation not brought within that time frame, “*the only remedy the reference product sponsor can get in that action is a reasonable royalty.*” *Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1058 (Fed. Cir. 2016) (emphasis added); *see also* 35 U.S.C. § 271(e)(6) (“the sole and exclusive remedy that may be granted by a court ... shall be a reasonable royalty.”) This limitation on damages for untimely, later-asserted patents is intended to disincentivize serial suits

after the biosimilar applicant has negotiated which patents should be immediately litigated. 35 U.S.C. § 271(e)(6)(A), (B); 42 U.S.C. § 262(l)(6)(B)). Regeneron's claim, which Mylan heard for the first time yesterday, that it will reduce the number of patents from 24 to six or less at some time in the litigation that suits it, will not only allow a second wave of litigation, but a second wave in which Mylan expects Regeneron still will lay claim to the full statutory damages rights available under the statute, including lost profits.

Accordingly, Regeneron's suggestion that it will, at some undefined point in the case, limit the number of patents and claims at issue here does nothing to address the unilateral and highly prejudicial strategic and economic advantage that Regeneron insists on holding over Mylan's head with respect to the patents that are not selected for trial. Moreover, if Regeneron were serious about streamlining the case, and genuine in its representations to Mylan and the Court, Regeneron should rely on the "extensive pre-suit disclosures" in the patent dance to select and play its best hand in the litigation *now*, dismissing or limiting the future scope of relief on any remaining patents, as contemplated by Mylan Proposal 2. To be clear, only Mylan's proposed schedules provide the necessary certainty across all 24 patents Regeneron has chosen to assert. (*See, e.g.*, Doc. 75, Exhibit B.)

Respectfully submitted this 29th day of September, 2022.

STEPTOE & JOHNSON PLLC

/s/ Gordon H. Copland

Gordon H. Copland (WVSB #828)
William J. O'Brien (WVSB #10549)
400 White Oaks Boulevard
Bridgeport, WV 26330
(304) 933-8162
gordon.copland@steptoe-johnson.com
william.obrien@steptoe-johnson.com

Of Counsel (admitted pro hac vice):

William A. Rakoczy
Heinz J. Salmen
Eric R. Hunt
Neil B. McLaughlin
Lauren M. Lesko
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 W. Hubbard St., Suite 500
Chicago, IL 60654
(312) 527-2157
wrakoczy@rmmslegal.com
hsalmen@rmmslegal.com
ehunt@rmmslegal.com
nmclaughlin@rmmslegal.com
llesko@rmmslegal.com

*Counsel for Defendant
Mylan Pharmaceuticals Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of September, 2022, I electronically filed the foregoing “**Defendant Mylan Pharmaceuticals Inc.’s Post-Hearing Supplement**” with the Clerk of the Court using the CM/ECF system, which will send notification of such filings to the following counsel of record:

David I. Berl
dberl@wc.com
Thomas S. Fletcher
tfletcher@wc.com
Teagan J. Gregory
tgregory@wc.com
Nicholas Jordan
njordan@wc.com
Kathryn S. Kayali
kkayali@wc.com
Arthur J. Argall, III
aargall@wc.com
Shaun P. Mahaffy
smahaffy@wc.com
Ellen E. Oberwetter
eoberwetter@wc.com
Adam Pan
apan@wc.com
Andrew V. Trask
atrask@wc.com
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, SW
Washington, DC 20024

David R. Pogue
drpogue@cdkrlaw.com
Steven Robert Ruby
sruby@cdkrlaw.com
**CAREY, DOUGLAS,
KESSLER & RUBY, PLLC**
707 Virginia Street, East
Suite 901
Charleston, WV 25301

Attorneys for Plaintiff Regeneron Pharmaceuticals, Inc.

/s/ Gordon H. Copland
Gordon H. Copland (WV Bar #828)
gordon.copland@steptoe-johnson.com
William J. O’Brien (WV Bar #10549)
william.obrien@steptoe-johnson.com
STEPTOE & JOHNSON PLLC
400 White Oaks Boulevard
Bridgeport, WV 26330
(304) 933-8000